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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,844

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Thomas W. Hodge

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EXAMINER

SWOPE, SHERIDAN

ART UNIT

PAPER NUMBER

1652

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/590,844	<b>Applicant(s)</b> HODGE ET AL.	
	<b>Examiner</b> SHERIDAN SWOPE	<b>Art Unit</b> 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6, 8-10, 15-26, 29-32, 34-41, 43-45 and 47-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-4, 6, 8-10, 15-26, 29-32, 34-41, 43-45, and 47-59 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-4, 6, 8-10, 15-26, 29-32, 34-41, 43-45, and 47-59 are pending.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-4, 6, 8-10, 15-26, 29-32, and 34, drawn to a method of decreasing infection by decreasing the activity of a Rab protein.

Group II, claim(s) 35-39, drawn to a method of treating infection in a patient by administering an agent that interferes with the interaction of a pathogen and a host protein.

Group III, claim(s) 40, 41, 43-45, 47, 48, drawn to a method for identifying an agent that decreases pathogenicity by decreasing Rab activity.

Group IV, claim(s) 49, drawn to a cell comprising a gene deletion.

Group V, claim(s) 50, drawn to a transgenic mammal comprising a gene deletion.

Group VI, claim(s) 51-53, drawn to a method for identifying a Rab modulator by detecting pathogenic infection in a cell.

Group VII, claim(s) 54-57, drawn to a method for determining resistance/susceptibility to pathogenic infection by comparing sequences.

Group VIII, claim(s) 58 and 59, drawn to a polynucleotide.

For each of Inventions I-VIII above, restriction to the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-VIII and one or more of the following inventions, as indicated.

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If Group I is elected, elect one of:

- (A.) In vivo
- (B.) In cell culture

If Group I is elected, elect one of:

- (C.) Rab9A
- (D.) Rab11A

If Group I is elected, elect one of:

- (E.) Decreasing activity of an activating modulator
- (F.) Increasing activity of an inhibitory modulator
- (G.) Decreasing mRNA levels
- (H.) Decreasing activity of a Rab and a Rab activating modulator

If (E) above is elected, elect one of:

- (ix.) a v-SNARE protein,
- (x.) a t-SNARE protein,
- (xi.) a GDP dissociation inhibitor,
- (xii.) a guanine-nucleotide exchange factor (GEF),
- (xiii.) a guanine-nucleotide displacement factor (GDF),
- (xiv.) mannose-6-phosphate receptor, TIP47,
- (xv.) a Rab9A effector
- (xvi.) a modulator other than (i)-(vii)

If (G) above is elected, elect one of SEQ ID NO: 5-9, 16-32, 47-66, or the genus of any compound other than said sequences

If Group I is elected, elect one of:

- (I.) Associated with SEQ ID NO: 1
- (J.) Associated with SEQ ID NO: 2
- (K.) Not associated with SEQ ID NO: 1 or 2

If Group I is elected, elect one of:

- (L.) Decreasing interaction of a pathogen and a Rab protein
- (M.) Decreasing interaction of a pathogen and a Rab modulator
- (N.) Decreasing expression of a Rab protein
- (O.) Decreasing expression of a Rab modulator

If (N) or (O) is elected, elect one of:

- (ix.) Transcriptional regulation
- (x.) Non-transcriptional regulation

If (ix) is elected, elect one of:

- (a) Insertional regulation of transcription
- (b) Anti-sense RNA
- (c) Triple helix molecule
- (d) Ribozyme
- (e) microRNA
- (f) siRNA
- (g) Non-insertional regulation of transcription other than (b)-(f)

If (f) above is elected, elect one of SEQ ID NO: 5-9, 16-32, one specific combination of said sequences, or the genus of any compound other than said sequences

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If (b) above is elected, elect one of SEQ ID NO: 47-56, one specific combination of said sequences, or the genus of any compound other than said sequences

If (d) above is elected, elect one of SEQ ID NO: 57-66 or the genus of any compound, one specific combination of said sequences, other than said sequences

If Group I is elected, also elect one of:

- (P.) A viral pathogen
- (Q.) A non-viral pathogen

If Group II is elected, also elect one of:

- (A.) Treatment for a prophylactic effect
- (B.) Treatment for a therapeutic effect

If Group II is elected, also elect one of:

- (C.) The host protein is Rab9A
- (D.) The host protein is Rab11A
- (E.) The host protein is a Rab9A activator
- (F.) The host protein is a Rab11A activator

If Group II is elected, also elect one of:

- (G.) The agent is a transcriptional regulator
- (H.) The agent is a non-transcriptional regulator

If Group II is elected, also elect one of:

- (I.) Anti-sense RNA
- (J.) Triple helix molecule
- (K.) Ribozyme
- (L.) microRNA
- (M.) siRNA
- (N.) An agent other than (I)-(M)

If Group III is elected, also elect one of:

- (A.) Rab9A
- (B.) Rab11A

If Group III is elected, also elect one of:

- (C.) Decreased expression
- (D.) Decreased enzymatic activity

If (C) is elected, elect one of:

- (ix.) Decreasing expression of a Rab
- (x.) Decreasing expression of a Rab modulator

If Group III is elected, also elect one of:

- (E.) A viral pathogen
- (F.) A bacterial pathogen
- (G.) A protozoan pathogen
- (H.) A pathogen other than (E)-(G)

If Group IV is elected, elect one of:

- (A.) Rab9A gene

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- (B.) Rab11A gene
- (C.) Rab9A activator gene
- (D.) Rab11A activator gene

If Group V is elected, elect one of:

- (A.) Rab9A gene
- (B.) Rab11A gene
- (C.) Rab9A activator gene
- (D.) Rab11A activator gene

If Group VI is elected, elect one of:

- (A.) In vivo
- (B.) In cell culture

If Group VI is elected, elect one of:

- (C.) Reduced expression of a Rab9A modulator
- (D.) Reduced expression of a Rab11A modulator

If Group VII is elected, elect one of:

- (A.) Rab9A first sequence
- (B.) Rab11A first sequence
- (C.) Rab9A modulator first sequence
- (D.) Rab11A modulator first sequence

If Group VII is elected, elect one of:

- (E.) A single first sequence
- (F.) A plurality of first sequences

If Group VIII is elected, elect one of SEQ ID NO: 5-9, 16-32, or 47-66.

The inventions listed as Groups I-VIII, and sub-inventions thereof, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I-VIII appears to be that they all relate to Rab proteins. However, Rab proteins were well known in the art. Moreover, Shapira et al, 1995 teach methods for identifying modulators of Rab9 (Table I), which anticipates Claim 40. Therefore Groups I-VIII share no special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art. Furthermore, the methods of Groups I-VIII do not use the same reagents or produce the same results.

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Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention and sub-inventions to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election

without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper. If Applicants should traverse the instant restriction based on an argument that the inventions or sub-inventions are not distinct, they should provide evidence as to why the skilled artisan would find any restricted inventions or sub-inventions obvious over their elected invention and sub-invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).



To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652